Data Processing Agreement

*Instructions: Fill out the table below incl. reference to the SaaS or Collaboration agreement.
For hospitals or physicians, Mentice will act as Processor and the hospital as Controller.
For device companies, Mentice will act as Sub-Processor and the device company as Processor.*

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| --- | --- |
| Date | 00/00/2023 |
| SaaS  | Ankyras |
| SaaS Agreement | SaaS Agreement titled [\_\_\_], entered into on [\_\_\_] 2023 |

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| --- | --- |
| Processing Role (select one) | [ ] Controller [ ] Processor [ ] Sub-Processor |
| Company Name | Mentice Spain S.L. |
| Company Identity No. | B72624646 |
| Address | Rambla de Catalunya 53-55 4H, 08007, Barcelona, Spain |
| Contact Person | Hector Fernandez |
| Telephone | - |
| Mobile | - |
| Email | ankyras@mentice.com  |

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| --- | --- |
| Processing Role (select one) | [ ] Controller [ ] Processor [ ] Sub-Processor |
| Company Name |  |
| Company Identity No. |  |
| Address |  |
| Contact Person |  |
| Telephone |  |
| Mobile |  |
| Email |  |

**1 - Purpose of the Agreement.** The parties seek to implement an agreement that governs the processing or sub-processing of personal data that complies with the requirements of the current legal framework in relation to data processing and with the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of Personal Data and on the free movement of such data (“GDPR”) and repealing Directive 95/46/EC (jointly “EU Data Protection Laws”).

This Agreement governs the processing of personal data by Processor or Sub-Processor on behalf of Controller or Processor, including the collection, registration, compilation, storage or disclosure of personal data, or combinations thereof, in connection with the licensing by Mentice AB (publ) or any Affiliate (“Mentice”) of certain services in accordance with the SaaS Agreement. Processor/Sub-Processor understands that Controller/Processor acts on behalf of customers etc. for the personal data covered by the SaaS Agreement and that Controller/Processor is subject to certain obligations under GDPR.

In addition to the terms defined in the foregoing, the following terms shall have the following meanings: “Agreement” means this Data Processing Agreement and all annexes, “Personal Data” means any personal data processed by Processor/Sub-Processor on behalf of Controller/Processor pursuant to or in connection with the SaaS Agreement, “Data Transfer” means (a) transfer of personal data from Controller/Processor to Processor/Sub-Processor; or (b) an onward transfer of personal data from Processor/Sub-processor to Sub-Processor/a third party sub-processor, “Services” means the services provided under the SaaS Agreement and the term “Affiliate” means a corporation or any other entity that directly, or indirectly through one or more intermediaries, is controlled by, or is under common control with, Mentice. As used herein, the term “control” means possession of direct or indirect power to order or cause the direction of the management and policies of a corporation or other entity whether (i) through the ownership of more than fifty percent (50%) of the voting securities of the other entity, or (ii) by contract, statute, regulation or otherwise. The terms “Data Subject”, “Personal Data Breach”, “Supervising Authority” and “Processing” shall have the same meaning as in the GDPR, and their cognate terms shall be construed accordingly.

This Agreement shall ensure that Personal Data is not used illegally, unlawfully or that such data is processed in ways that lead to unauthorized access, alteration, deletion, damage, loss or inaccessibility of the data.

**2 - Processing of Personal Data.** Controller/Processor instructs Processor/Sub-Processor to process Personal Data. Processor/Sub-Processor shall: (a) comply with all applicable Data Protection Laws in the Processing of Personal Data; and, (b) not process personal data other than on the Controller’s/Processor’s documented instructions.

**3 - Processor/Sub-Processor Personnel.** Processor/Sub-Processor shall take reasonable steps to ensure the reliability of any employee, agent or contractor of Processor/Sub-Processor who may have access to Personal Data, ensuring in each case that access is strictly limited to those individuals who need to know/access the relevant Personal Data as strictly necessary for the purposes of the SaaS Agreement, and to comply with applicable laws in the context of that individual’s duties, ensuring that all such individuals are subject to confidentiality undertakings or professional or statutory obligations of confidentiality.

**4 - Security.** Taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of Processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons, Processor/Sub-Processor shall in relation to Personal Data implement appropriate technical and organizational measures to ensure a level of security appropriate to that risk, including, as appropriate, the measures referred to in Article 32(1) of the GDPR. In assessing the appropriate level of security, Processor/Sub-Processor shall take account in particular of the risks that are presented by Processing, in particular from a Personal Data Breach perspective.

**5 - Sub processing.** Processor/Sub-Processor shall appoint or disclose any Personal Data to a sub-processor only if authorized in writing by Controller/Processor and provided any such sub-processor enters into a written agreement on terms and conditions comparable to those set forth herein.

**6 - Data Subject’s Rights.** Taking into account the nature of the Processing, Processor/Sub-Processor shall assist Controller/Processor by implementing appropriate technical and organisational measures, insofar as this is possible, for the fulfilment of Controller’s/Processor’s obligations, as reasonably understood by Processor/Sub-Processor, to respond to requests to exercise Data Subject’s rights under the Data Protection Laws. Processor/Sub-Processor shall (a) promptly notify Controller/Processor if it receives a request from a Data Subject under any Data Protection Law in respect of Personal Data; and (b) ensure that it does not respond to that request except on the documented instructions of Controller/Processor or as required by applicable laws to which Processor/Sub-Processor is subject, in which case Processor/Sub-Processor shall to the extent permitted by applicable laws inform Controller/Processor of that legal requirement before Processor/Sub-Processor responds to the request.

**7 - Personal Data Breach.** Processor/Sub-Processor shall notify Controller/Processor without undue delay upon Processor/Sub-Processor becoming aware of a Personal Data Breach affecting Personal Data, providing Controller/Processor with sufficient information to allow Controller/Processor to meet any obligations to report or inform Data Subjects of the Personal Data Breach under the Data Protection Laws. Processor/Sub-Processor shall co-operate with Controller/Processor and take reasonable commercial steps as are directed by Controller/Processor to assist in the investigation, mitigation and remediation of each such Personal Data Breach.

**8 - Data Protection Impact Assessment and Prior Consultation**. Processor/Sub-Processor shall provide reasonable assistance to Controller/Processor with any data protection impact assessments, and prior consultations with Supervising Authorities or other competent data privacy authorities, which Controller/Processor reasonably considers to be required by Article 35 or 36 of the GDPR or equivalent provisions of any other Data Protection Law.

**9 - Deletion or return of Company Personal Data.** Subject to this Sec. 9, Processor/Sub-Processor shall promptly and in any event within 10 business days of the date of cessation of any Services involving the Processing of Personal Data, delete and procure the deletion of all copies of those Personal Data.

**10 - Audit rights.** Subject to this Sec. 10, Processor/Sub-Processor shall make available to Controller/ Processor on request all information necessary to demonstrate compliance with this Agreement, and shall allow for and contribute to audits, including inspections, by Controller/Processor or an auditor mandated by Controller/Processor in relation to the Processing of Personal Data. Information and audit rights of Controller/Processor only arise under this provision to the extent that the Agreement does not otherwise provide for information and audit rights meeting the relevant requirements of Data Protection Law.

**11 - Data Transfer.** Processor/Sub-Processor may not transfer or authorize the transfer of Personal Data to countries outside the EU and/or the European Economic Area (EEA) without the prior written consent of Controller/Processor. If Personal Data processed under this Agreement is transferred from a country within the European Economic Area to a country outside the European Economic Area, the parties shall ensure that the Personal Data is adequately protected. To achieve this, the parties shall, unless agreed otherwise, rely on EU approved standard contractual clauses for the transfer of Personal Data.

**12 - Miscellaneous.** Each party must keep this Agreement and information it receives about the other party and its business in connection with this Agreement confidential, and must not use or disclose that confidential information without the prior written consent of the other party except to the extent that: (a) disclosure is required by law, (b) the relevant information is already in the public domain.

All notices and communications given under this Agreement must be in writing and will be delivered personally, sent by post or sent by email to the address or email address set out in the heading of this Agreement at such other address as notified from time to time by the parties changing address.

## **13 - Term.** This Agreement shall remain effective as long as Processor/Sub-Processor processes Personal Data on behalf of Controller/Processor under the SaaS Agreement.

**14 - Choice of Law and Disputes.** This Agreement is governed by Spanish law. Any action or proceedings by Controller/Processor against the Processor/Sub-Processor may be brought by Controller/Processor in any court(-s) having jurisdiction over Processor/Sub-Processor. Any actions or proceedings by Processor/Sub-Processor against Controller/Processor may be brought by Processor/Sub-Processor only in the court(-s) having jurisdiction over the location of Controller/Processor.

Mentice Spain S.L. [NN]

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| By: | **\si2\** |  | By: | **\si1\** |
|  |  |  |  |  |
| Name: | \na2\ |  | Name: | \na1\ |
|  |  |  |  |  |
| Title: | \ti2\ |  | Title: | \ti1\ |
|  |  |  |  |  |
| Date: | \ds2\ |  | Date: | \ds1\ |

**ANNEX 1**

## 1. Purpose

The purpose of the parties' processing of personal data under the Agreement is:

Subscription Services for pre-operative planning: All Mentice Spain S.L. Subscription Services, including but not limited to the Ankyras online service (accessible from [www.ankyrasonline.com](http://www.ankyrasonline.com)).

## 2. Types of personal data

The following types of personal data will be processed by the parties under the Agreement:

* Case data including patient data included on the DICOM tags attributes as the standard for the communication and management of medical imaging information and related data. This data can be anonymized by the Controller/Processor before being used on the subscription services. The use of patient data is done under consent obtained by Controller/Processor from its patients and under its sole responsibility.
* Personal data used to assign Controller/Processor with a unique identification number (ID number) that allows Mentice Spain S.L. to identify and provide Controller/Processor with the Subscription Services. The ID number will uniquely identify Controller/Processor if Controller/Processor signs up using the same account on a new device.

## 3. Categories of personal data

Mentice Spain S.L. collects the following personal data when the users first sign up on any of the Mentice Spain S.L. Subscription Services (such as [www.ankyrasonline.com](http://www.ankyrasonline.com)):

* Name
* E-mail address
* Controller/Processor’s affiliation
* Country where the Controller/Processor is located
* User’s role with the Controller/Processor
* Telephone number (optionally)

## 4. Processing operations

## Personal and Case Data will be Processed in accordance with the Agreement and may be subject to the following Processing activities:

## Storage and other Processing necessary to provide, maintain and improve the Subscription Services provided to Controller/Processor; and/or

## Disclosure in accordance with the Agreement and/or as compelled by applicable laws.

## 5. List of Sub-Processors

The parties have agreed that the following subcontractors may be used by the respective parties under the Agreement. Sub-Processors may change from time to time and may include third parties or Mentice Spain S.L.’s Affiliates.

For the most recent list of Sub-Processors, please refer to the Mentice Spain S.L. privacy policy webpage: <https://www.mentice.com/ankyras/privacy-policy>